(b) *Effect of exemption.* (1) In general, intraocular lenses are exempted from provisions of the following sections of the act and regulations thereunder when an application for exemption applicable to the lenses is in effect under this part: Misbranding under section 502, registration and premarket notification under section 510, performance standards under section 514, premarket approval under section 515, records and reports under section 519, restricted devices under section 520(e), good manufacturing practices under section 520(f), and color additives under section 721.

(2) Intraocular lenses shall not be extempted from a provision of the act listed in paragraph (b)(1) of this section where the Commissioner indicates that the lens is not exempt from such a provision in an order of disapproval, approval, or approval with modifications under §813.30.

[42 FR 58889, Nov. 11, 1977, as amended at 59 FR 14366, Mar. 28, 1994]

§813.2 Applicability.

This part applies to all implantations of intraocular lenses in humans unless a premarket approval application has been approved for these lenses under section 515 of the act.

§813.3 Definitions.

(a) *Intraocular lens* means a lens intended to replace surgically the natural lens of the human eye. An intraocular lens is, for purposes of this part, synonymous with ''investigational device,'' lens, or lenses.

(b) *Investigational device* means a device that is used in an investigational study involving human subjects, where the study is for the purpose of determining if the device is safe or effective.

(c) *Investigational plan* means a plan or protocol for using an investigational device in an investigational study. See §813.25 for requirements applicable to an investigational plan.

(d) *Investigational study* means a study involving human subjects when the study is for the purpose of determining if an investigational device is safe or effective and includes any implantation in a human of an intraocular lens for which there is no approved application for premarket approval under section 515 of the act.

(e) *Investigator* means an individual who actually conducts an investigational study, i.e., under whose immediate direction the investigational device is administered or dispensed to, or used involving, a subject.

(f) *Monitor,* when used as a noun, means an individual selected by a sponsor or contract research organization to oversee the progress of an investigational study. The monitor may be a full-time employee of a sponsor or contract research organization or a consultant to the sponsor or contract research organization. (*Monitor,* when used as a verb, means the act of reviewing the progress of an investigational study.)

(g) *Sponsor* means a person who initiates an investigational study, but who does not actually conduct the study (i.e., the investigational device is administered or dispensed to, or used involving, a subject under the immediate direction of another individual). A person other than an individual, e.g., corporation or government agency, that uses one or more of its own employees to conduct an investigational study that it has initiated is considered to be a sponsor (not a sponsor-investigator), and the employees are considered to be investigators.

(h) *Sponsor-investigator* means an individual who both initiates and actually conducts, alone or with others, an investigational study (i.e., under whose immediate direction the investigational device is administered or dispensed to, or used involving, a subject). The term does not include any person other than an individual. Any sponsor-investigator shall carry out the responsibilities under this part of a sponsor and of an investigator.

(i) *Institution* means a person (other than an individual) who engages in the conduct of research on human subjects or in the delivery of medical services to human subjects as a primary activity or as an adjunct to providing residential or custodial care to human beings. The term includes a hospital, retirement home, prison, university, or device manufacturer. Facility as used in section 520(g) of the act is deemed to by synonymous with the term institution for purposes of this part.

(j) *Subject* means an individual who is or becomes a paticipant in an investigational study, either as a recipient of the investigational device or as a control. A subject may be either a nonpatient volunteer or a patient on whom the intraocular lens might have a therapeutic effect.

(k) *Person* includes an individual, partnership, corporation, association, scientific establishment, government agency, and any other legal entity.

(l) *Institutional review committee* means a committee (appointed by an institution to review and monitor investigations in which human subjects participate) whose major responsibility is the protection of human subjects from risk to their health, safety, or dignity in accordance with the current professional standards and the requirements of this part. Such a committee may be known as an institutional review board or by other names.

§813.5 General qualifications for an exemption.

A shipment of an intraocular lens is exempt from any or all the otherwise applicable requirements of the act enumerated in §813.1(b)(1) if all the following conditions are met:

(a) The label of the device bears the following: the name and place of business of the manufacturer, packer, or distributor in accordance with §801.1 of this chapter; the quantity of contents; the sterility shelf life of the lens; and the statement, ''Caution—investigational device. Limited by Federal (or United States) law to investigational use''.

(b) The labeling of the intraocular lens is not false or misleading in any particular.

(c)(1) An application for investigational device exemption covering that shipment was submitted by the sponsor under Subpart B of this part, and the requisite time has elapsed following the date of receipt of the application by the Food and Drug Administration to permit the investigational study to begin under §813.30(b).

(2) The Commissioner has not disapproved the application or withdrawn the exemption.

(3) Each shipment of the intraocular lens is made in accordance with the commitments in the application and any conditions imposed in the Commissioner's approval of the application.

(4) The sponsor has complied with the requirements of Subparts B, C, and G of this part, any institutional review committee that is to review and approve the investigational study for which shipment is made has complied with the requirements of Subparts D and G of this part, and the investigator(s) to which the shipment is to be made has complied with the requirements of Subparts E and G of this part and with the requirements for informed consent contained in Part 50 of this chapter.

(d) If the shipment is to be imported into or exported from the United States, the requirements of §813.19 have been met.

[42 FR 58889, Nov. 11, 1977, as amended at 47 FR 46079, Oct. 15, 1982]

§813.10 Petitions for waiver of requirements.

(a) Any person subject to any requirement under this part may petition the Commissioner for a waiver of such requirement. Such a petition shall be submitted in accordance with §10.30 of this chapter and shall set forth the basis for the petitioner's belief that compliance with the requirement is not necessary to achieve the objectives of this part and, where appropriate, any alternative means to achieve the objective of the requirement from which the waiver is sought.

(b) The Commissioner may, at his discretion, grant a petition for a waiver submitted under this section if he finds that compliance with the requirement from which the waiver is sought is not necessary to achieve the objectives of this part and, where appropriate, that the proposed alternative means will achieve the objective of the requirement from which the waiver is sought.

(c) The person who submits a petition under this section continues to be subject to the requirement from which the waiver is sought unless and until the Commissioner grants the petition.